DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service 93775d

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA CERTIFIED MAIL

WARNING LETTER

FLA-03-17

December 17, 2002

Ronald V. Annechiarico, President
Eastern Medical Equipment Distributors, Inc.
1625 West McNab Road, Suite #12
Pompano Beach, Florida 33069

Dear Mr. Annechiarico,

The Food and Drug Administration (FDA) inspected your medical gas facility located at the above address on September 18, 2002. Medical gases are drugs as defined by section 201 (g) (21 U.S.C. 321 (g)) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection found significant deviations from the Current Good Manufacturing Practice (CGMP) regulations for drug products, set forth in Title 21, Code of Federal Regulations (21 CFR), Part 210 and 211, These deviations cause the medical Oxygen USP you transfill to be adulterated within the meaning of section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) of the Act, in that the methods used in, or the facilities or controls used for, their manufacturing, processing, packing, storage, or holding, are not in compliance with CGMP.

The deviations include the following:

1. Failure to establish and implement scientifically sound and appropriate procedures to assure that your drug products conform to standards of identity, strength, quality, and purity as required by 21 CFR 211.160. Your firm has not established any written testing program or product specifications. Available written procedures fail to identify and define the pre-fill, fill, and post-fill checks to be performed on Oxygen USP cylinders filled at your facility. In addition, your firm failed to have any written procedure for use of your Oxygen Analyzer and failed to retain the manufacturer issued operator's manual [21 CFR 211.160(a)].

2. Failure to conduct appropriate laboratory determination of conformance to final specifications including the identity and purity of Oxygen USP prior to release of transfilled cylinders for distribution, as required per 21 CFR 211.165. Your firm failed to conduct all appropriate pre-fill, fill, and post fill checks on Oxygen USP cylinders transfilled at your facility.

3. Failure to properly calibrate the Oxygen Analyzer used for the assay of Oxygen, USP, in that your firm did not have a calibration program defining suitable intervals for calibration [21 CFR 211.160(b)(4)]. Therefore, no assurance could be provided that the current calibration procedures for the Servomex Oxygen Analyzer, Model 570A, which is used to check purity of your medical oxygen are appropriate. In addition, our investigation found that your firm failed to possess any calibration standards at the time of the inspection. Your firm also failed to maintain records of the periodic calibration of the Oxygen Analyzer, [21 CFR 211.194(d)].

4. Failure to test each component lot of bulk compressed oxygen to determine conformance with appropriate specifications prior to use, or in lieu of such testing, receive a valid certificate of analysis for each lot from your supplier and conduct an identity test as required by 21 CFR 211.84(d)(2).

5. Failure to establish written procedures describing the responsibilities and authorities of the Quality Control Unit (QCU) as required by 21 CFR 211.22. You have no written procedures for a QCU, nor do you have a defined QCU established at your facility. In addition, your production and control records are not reviewed by a QCU, in accordance with 21 CFR 211.192.

6. Failure to routinely calibrate mechanical and electronic equipment used in the transfilling of Oxygen USP or keep records of calibration according to a written program designed to assure proper performance as required by 21 CFR 211.68. For example, there was no documentation that your temperature recording device, the vacuum gauge, and the pressure gauges for the manifold filler have ever been calibrated.

7. Failure to establish and implement an effective employee CGMP training program. There was no documentation that demonstrates that any of the employees involved in the transfilling and storage of Oxygen U.S.P. have received training for those operations [21 CFR 211.25(a)].

8. Failure to establish adequate batch production and control records for each batch of drug product, including documentation that each significant step in the filling operation was performed [21 CFR 211.188]. The inspection revealed that your firm failed to maintain any batch production records for lots transfilled prior to August 24, 2002. The batch record dated August 24, 2002 does not document all pre-fill, fill, and post-fill checks performed. It is unacceptable to use a single entry to indicate that all of the required steps in the operation were performed. Your purity test result should record the actual numeric assay value obtained with the Oxygen Analyzer rather than a checkmark [21 CFR 211.194].

9. Failure to establish written procedures describing a system by which the distribution of each lot of drug product filled by your firm can be readily determined to facilitate its recall if necessary [21 CFR 211.150(b)].

10. Failure to have written procedures for handling all written and oral complaints regarding your drug products as required by 21 CFR 211.198.

11. Failure to establish written procedures designed to assure that correct labels and labeling are used, including identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch [21 CFR 211.130(c)].

Review of your labeling used on cylinders of compressed medical oxygen filled by your firm also reveals the products to be misbranded with the meaning of Sections 502(b)(1) of the Act in that your current label fails to bear the place of business of your firm. Your labels identify your company name but fail to at least reference your business city and state for consumers to contact your firm as needed about your products.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all requirements of the Act and its implementing regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. Possible actions include, but are not limited to, seizure and/or injunction.

Within fifteen (15) working days of receipt of this letter, please notify this office in writing of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Please send your reply to the Food and Drug Administration, Attention: Shari J. Hromyak, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Ms. Hromyak at (407) 475-4730.

Sincerely,

Emma R. Singleton
Director, Florida District